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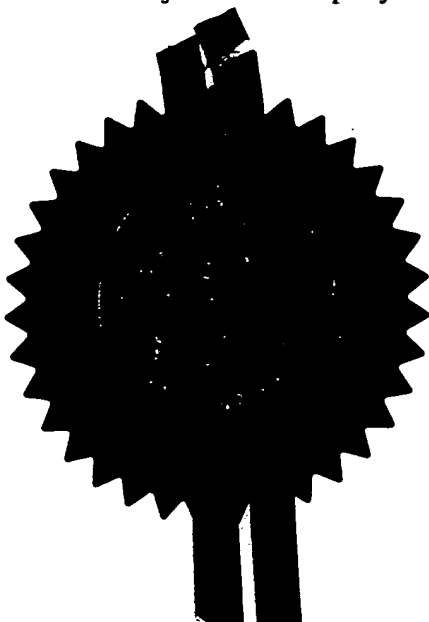
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Dated

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GM/99090 GB

2. Patent application number

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772992K001

UNITED KINGDOM

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

METAL-CONTAINING COMPOSITIONS, PREPARATIONS AND USES

5. Name of your agent (if you have one)

BATCHELLOR, KIRK & CO.,

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LONDON EC1M 5SA.

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Country

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8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

a) any applicant named in part 3 is not an inventor, or

b) there is an inventor who is not named as an applicant, or

c) any named applicant is a corporate body.

See note (d))

YES

"Metal-containing Compositions, Preparations and Uses"

It is well established that minerals i.e. traces of selected metal elements are required as part of the human diet for good health. Mineral deficiencies can lead to poor health and specific disorders. Amongst the minerals that the body requires, there are, for example, the metals zinc, magnesium, copper, iron, and selenium. The human body requires traces of such minerals in soluble form whereby the corresponding metallic ions are bio-available within the bloodstream.

With the increase in highly processed and convenience foods, there are concerns that the typical diet in today's conditions may not contain sufficient vitamins and/or minerals. Accordingly vitamin and mineral supplements are widely available without prescription on the basis that they are foodstuff components and not medicaments.

This invention is particularly concerned with mineral metal compositions, their preparation and uses within a mineral 'delivery' system for humans or animals. It is known that mineral salts by themselves, e.g. zinc sulphate, iron sulphate and the like will dissociate in aqueous solution to form the corresponding ions e.g. Zn^{2+} and Fe^{2+} with SO_4^{2-} . However, it has been observed that such ions in solution within the bloodstream are not readily bio-available in the sense of being available for uptake by cells. Accordingly there are at least two mineral 'binder' systems available for enhancing bio-availability of these ions. Most mineral supplement compositions presently available are based upon an inorganic chelate binder system. In such compositions, the required mineral element e.g. zinc, magnesium or the like is chemically bonded to a chelate but in such a manner that bio-availability of the mineral ions is still significantly impaired. The digestive system has difficulty in leaching the mineral element away from the chelate binder for cellular uptake. This limits their bio-availability. Chelate based mineral supplements apparently limit the body's absorption of the elemental mineral to some 7 to 10% of that presented. It is suggested that the remaining mineral content is not

absorbed into the bloodstream, but is passed in the urine or faeces. Chelate-bound iron mineral supplements, in particular, can cause constipation as the chelate can act as a flocculent in the large intestine. It is desirable that such disadvantage be overcome in an alternative mineral 'delivery' system with improved bio-availability of the mineral elements.

Another mineral supplement composition is based upon a mineral salt combined with an organic glutamate binder. One product based upon the glutamate bound mineral delivery system is a lozenge containing zinc for oral ingestion. However, not only does the glutamate delivery system demonstrate restricted mineral element/ion bio-availability in similar fashion to the chelates described above, but also zinc glutamate lozenges in particular tend to leave undesirable coloured stains in the mouth. Accordingly it is also desirable to overcome this particular disadvantage in an alternative mineral delivery system providing better mineral element bio-availability.

In consequence it can be summarised that the existing chelate and glutamate bound mineral compositions deliver such mineral elements into the bloodstream but only a small proportion of the total content of the respective mineral element, and over a relatively lengthy period of time whereby specific mineral bio-availability is limited.

The present inventor has considered the existing mineral delivery systems such as the chelate and glutamate delivery systems and their disadvantages. The present invention provides inter alia, alternative mineral delivery systems based on quite different components which have been found to improve specific mineral bio-availability in terms of not only bloodstream quantities but also bloodstream absorption time.

The present inventor provides several aspects to his invention, based upon mineral or other metallic element – containing compositions, methods for preparing such compositions and uses of such compositions which encompass several distinct technical fields apart from the field of mineral supplements for the human or animal diet, namely

uses of the compositions for treating or purifying water or sewage, use as an algacide, fungicide and disinfectant and uses in treating metal substrates to control corrosion.

Accordingly in a first aspect of this invention there is provided a metal-containing composition substantially comprising:

- 5 (i) at least one water soluble metal compound which forms metal ions when dissolved in water,
- (ii) at least one metal ion modifier as herein defined,
- (iii) at least one acid, and
- (iv) water
- 10 said composition having a pH of less than 6 and an electrolytic potential in excess of 10 millivolts.

Such compositions preferably essentially consist of the aforesaid components with any preferred additives and more preferably consist of such ingredients, optional additives and the balance being any inevitable impurities.

- 15 In a second aspect of this invention there is provided a method of making a composition as defined in the first aspect comprising dissolving (i) in distilled water, adding (ii) and mixing or allowing to dissolve, then adding (iii) whilst simultaneously monitoring the pH and electrolytic potential of the composition until a required value of each measurement is obtained.

- 20 A third aspect of this invention provides the use of a composition as defined in the first aspect in medicine, for example the use of such a composition for treating one or more of the following pathogenic disorders, namely bacterial, fungal or viral infection particularly including copper containing such compositions for treating one or more of the following diseases, namely cholera, salmonella, shigella, E.Coli and chlamydia.

- 25 A fourth aspect of this invention provides the use of a composition as defined in the first aspect, in the preparation of a medicament for use in the treatment of a disease or disorder, such as one or more of the aforementioned diseases or disorders.

The invention also provides in a fifth aspect the use of a composition as defined in the first aspect in the treatment of water or water containing materials or sewage, effluent, commercial, domestic waste products as a bactericide, or algacide, flocculent viricide and/or fungicide.

5 A sixth aspect of the present invention provides the use of a composition as defined in the first aspect to form a corrosion resistant coating or plating for metal substrates, to act as a sealant against metal corrosion.

In a seventh aspect the present invention provides the use of a composition as defined in the first aspect as a bactericidal and/or fungicidal preservative against the
10 bacterial or fungal deterioration of edible foodstuffs.

The metal ion modifier is preferably a binder other than chelate or glutamate effective to transport ions incorporating the metallic mineral element through the digestive system and into the bloodstream in bioavailable form. Such binder can be, for example, a complexing or sequestering agent. It is most preferred to use soluble
15 ammonium compounds.

The present invention is based on the inventor's discoveries that an improved metallic mineral delivery system for the human or animal bloodstream and other uses can be formulated from selected metal-containing electrolytes in acidic aqueous media which demonstrate a measurable electrolytic potential. Such compositions have
20 surprisingly been found, inter alia, when ingested or absorbed to make the mineral ions more rapidly available to the body for cellular uptake, and more efficiently in terms of percentage by weight of bio-available mineral within the bloodstream, after a given time. Additionally it would appear that the ions incorporating the metallic mineral element are more bio-active due to enhanced beneficial effects which have been observed.

25 Accordingly, within the present compositions, the metallic element effects appear to be synergistically improved by the metal ion modifier. In particular this appears to be the case with zinc and magnesium compositions.

In preferred embodiments of the invention, the metal compositions are mineral metal such compositions and can act transdermally by passing through the skin, mucosa or other mucous membrane, for even more rapid absorption into the bloodstream.

Preferred embodiments of the compositions for dietary supplement or medical uses
5 can provide up to 90% by weight of the mineral element absorbed into the bloodstream, in bio-available and potentially more bio-active form in up to 10 minutes e.g. within 6 to 10 minutes. Accordingly such compositions for dietary or medical uses in the form of acidic aqueous electrolyte solutions can provide for rapid mineral element ion delivery to the body for cellular uptake, with less wastage of the desirable mineral passing in the
10 urine and/or faeces.

In the case of preferred compositions which contain iron or zinc as the mineral element, it is possible to avoid the disadvantages of chelated iron and zinc glutamate mentioned above, whilst simultaneously providing more of these mineral elements available in the bloodstream in less time and again apparently in a more bio-active form.

15 The present compositions for human or animal dietary or medical use are preferably based upon the presence of at least one water soluble metal compound such as a mineral metal salt in aqueous compositions which further contain components as defined in the first aspect and all of which said components have been designated GRAS (generally regarded as safe) food additives or other chemicals by the US-FDA

20 In order to make the present compositions for human or animal dietary or medical use, it is preferred for the following general preparative procedure to be adopted:

General Procedure

(a) The required metal such as a mineral element e.g. zinc is included by way of a soluble salt of the metal such as zinc sulphate. This is to be completely dissolved in
25 distilled water (in contrast to deionised water) by mixing the salt into the water at ordinary room temperature, by vigorous stirring. The corresponding metallic mineral ions thereby form in the aqueous solution.

(b) When all the metallic salt has been completely dissolved in the distilled water, at least one metal ion modifier is added, preferably a sequestering or complexing agent such as one or more soluble ammonium salts, for example one or more of: ammonium sulphate, ammonium chloride, ammonium citrate, and ammonium phosphate, which is
5 mixed into the solution to dissolve therein.

(c) To the aqueous mixture, obtained in step (b), at least one acid component (e.g. sulphuric and/or citric acid or hydrochloric acid) is added carefully and slowly, preferably by measured metering, to lower the pH of the mixture to a preferred level and to simultaneously exhibit a measurable electrolytic potential until a preferred level thereof is
10 also reached. The value of electrolytic potential is preferably measured and monitored by milli-voltmeter. Several commercially available instantaneous readout pH meters can function as a milli-voltmeter by simple adjustment. Sufficient acid should be added so as to control the values of pH and electrolytic potential. This process for making the aqueous metal-containing compositions, particularly mineral metal such compositions for
15 dietary or medical use, can be likened to a form of electrometric titration.

The inventor has observed that in many embodiments, after completion of step (c) - the addition of one or more appropriate acids, most preferably GRAS designated acids, the compositions exhibit behaviour associated with dynamic equilibrium solutions at relatively high electrolytic potential. An exothermic reaction during step (c) may be
20 observed. The aqueous compositions in many embodiments also appear to demonstrate the characteristics of an overall cationic solution in which positively charged cations including the metallic element outnumber the anions. Furthermore such cations when present in the bloodstream appear to be attracted to and thereby damage or destroy pathogenic cells having an overall negative charge, such as bacterial, fungal or viral
25 cells.

In order that the invention in all its aspects may be further elucidated a plurality of non-limiting examples are now presented in tabular form for a more complete

appreciation of the invention, and to enable these and other embodiments of the invention to be reduced to practice by one of ordinary skill in the art. The preparative procedure in each example corresponds to the general procedure already outlined above.

Copper		Copper Sulphate 150g	Ammonium Chloride 75g	Hydrochloric acid-concentrated variable	-	1-2	> 350	As example 3	
Copper		Copper Sulphate 150g	Ammonium Chloride 75g	Hydrochloric acid-concentrated variable	-	1-2	350	Medical, fungicide, oral and/or topical formulations	
Zinc		Zinc Sulphate 150g	Ammonium Chloride 75g	Hydrochloric acid-concentrated variable	-	1-2	> 350	Medical, antiviral	
Copper		Copper Sulphate 200g	Ammonium Sulphate 75g	Sulphuric acid 98% variable	-	1-2	> 350	Water purification - disinfectant	
Copper		Copper Sulphate 200g	Ammonium Sulphate 75g	Sulphuric acid 98% variable	-	1-2	> 350	Water treatment - algaeicide	
Copper		Copper Sulphate 200g	Ammonium Sulphate 75g	Sulphuric acid 98% variable	-	1-2	> 350	Water treatment - swimming pool disinfectant	
Copper		Copper Sulphate 200g	Ammonium Sulphate 75g	Sulphuric acid 98% variable	-	1-2	> 350	Sewage treatment - disinfectant	
Iron		Iron Sulphate 150g	Ammonium Sulphate 75g	Sulphuric acid 98% variable	-	1-2	> 350	Water treatment - flocculent	
Copper		Copper Sulphate 150g	Ammonium chloride 75g	Hydrochloric acid-concentrated variable	-	1-2	> 350	As example 1	

Copper	Copper Sulphate 150g	Ammonium chloride 75g	Hydrochloric acid-concentrated variable	-	1-2	> 350	As example 26
Copper	Copper	Ammonium chloride 75g	Hydrochloric acid-concentrated variable	-	1-2	> 350	Sewage treatment - disinfectant for sewage solids
Copper	Copper Sulphate 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	-	1-2	> 350	Food preservation fungicide-spray for fruit and vegetables
Copper	Copper Sulphate 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	-	1-2	> 350	Food preservation - meat disinfectant
Copper	Copper Sulphate 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	Fructose	1-2	> 350	Flower, tree and shrub preservation e.g. Christmas trees - bactericide and fungicide
Copper	Copper Sulphate 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	-	1-2	> 350	Food preservation seafood preservative
Copper	Copper Sulphate 150g	Ammonium Sulphate 75g	Sulphuric 98% variable	-	1-2	> 350	Food preservation - for fruit and vegetables
Copper	Copper Sulphate 150g	Ammonium Chloride 75g	Hydrochloric acid-concentrated variable	-	1-2	> 350	Food preservation- food processing area sanitiser
Copper	Copper sulphate 300g	Ammonium sulphate 82.5g	Sulphuric 98% variable	-	1-2	> 350	Metal preservation - metal sealing, plating and anti-corrosion
Nickel	Nickel sulphate 300g	Ammonium sulphate 82.5g	Sulphuric 98% variable	-	1-2	> 350	As example 38

Nickel	Nickel sulphate 200g	Ammonium sulphate 75g	Sulphuric 98% variable	Zinc sulphate	1-2	> 350	Industrial-algaecide and bactericide particularly in cooling towers to inhibit legionella bacteria
Titanium	Titanium sulphate 300g	Ammonium sulphate 82.5g	Sulphuric 98% variable	-	1-2	> 350	As example 38
Vanadium	Vanadium sulphate 300g	Ammonium sulphate 82.5g 1	Sulphuric 98% variable	-	1-2	> 350	As example 38
Zinc	Zinc sulphate 150g	Ammonium phosphate 75g	Phosphoric acid variable	Citric acid	1-2	> 350	Medical, for use in repairing impaired/damaged mitochondria e.g. in patents with AIDS presently taking more than one AIDS treatment drug.
Magnesium	Magnesium sulphate 150g	Ammonium phosphate 75g	Phosphoric acid variable	Malic acid	1-2	> 350	Medical, for use in repairing impaired/damaged mitochondria e.g. in patents with AIDS presently taking more than one AIDS treatment drug.
Zinc	Zinc sulphate 150g	Ammonium phosphate 75g	Phosphoric acid variable	Citric acid and Pyruvic acid	1-2	> 350	Medical - for use in treating ME chronic fatigue syndrome
Magnesium	Magnesium sulphate 150g	Ammonium phosphate 75g	Phosphoric acid variable	Malic acid	1-2	> 350	Medical - for use in treating ME chronic fatigue syndrome

N.B. variable denotes amount adjusted to obtain required specific pH and mV values, low pH and high mV being preferred.

From these examples it will be appreciated that the compositions may include one or more other additional components, besides the metal such as the preferred mineral, metal ion modifier, acid and water. By way of example, in zinc mineral compositions for dietary supplements or medical use it is preferred to incorporate one or more of the water soluble vitamins C, B5 and B6, each of which appear to play a role in accelerating delivery of the zinc mineral to cells via the bloodstream, to enhance the beneficial zinc ion effects.

In the case of magnesium mineral compositions for treating or preventing viral infections, it is preferred to include vitamins B1 and B3 to promote or synergise such beneficial anti-viral properties of the magnesium ion.

In the case of magnesium mineral compositions for treating chronic fatigue syndrome, it is preferred to include malic acid because it is useful for the same purpose. Compositions based on magnesium for treating PMT (pre-menstrual tension) preferably also include a natural diuretic to relieve water retention and for such compositions intended to treat insomnia, it is preferred also to include known sleep enhancers such as valerian or rapid eye movement extenders such as melatonin.

Zinc mineral compositions intended for enhancing vitality and for countering the effects of tiredness may further contain one or more of the following or other stimulants: caffeine, nicotine and ginseng.

The present compositions when used as a mineral source for rapid ingestion can demonstrate the following properties and advantages:

- (1) An ability to bind metal ions, eg from salts through the action of at least one metal ion modifier within the acidic, electrolytically active aqueous solution. In this regard, the metal ion modifier appears to act as a binder and/or buffering agent which links up with the metal ions, and which 'buffers' those desirable metal ions against removal from the bloodstream.

- (2) An ability to deliver and retain those mineral metals in an ionically modified form in the human or animal bloodstream through the buccal mucosa, oesophagus or stomach rapidly, i.e. within a few minutes.
- (3) The ionically modified mineral metal ions appear to remain in the blood serum to facilitate bio-availability of the specific mineral metal for cellular uptake, and moreover, certain effects which have been observed appear to indicate that it is not only the bio-availability which is enhanced, but also and quite surprisingly the bioactivity of the mineral.
- (4) The ionically modified mineral metal ions retain a net positive electrical charge which interacts with negatively charged virus, bacteria or fungal cells, forming a complex with these pathogens.
- (5) The ionically modified mineral metal ions in solution carry and appear to have the ability to deliver an electrical charge. This charge coupled with the overall mineral metal delivery system and the selected mineral metals help to control pathogens (bacteria, fungi and virus) apparently by degrading their membranes, complexing the pathogens thereby rendering them inactive or otherwise unable to harm the host's body. In this regard the present mineral metal compositions when delivered into the bloodstream, help the body's natural immune system to fight infection.
- (6) Substantially improved bio-availability of the mineral in the bloodstream after digestion or absorption in terms of mineral quantity and substantially reduced time for the mineral to become bio-available after digestion or absorption i.e. rapid absorption.
- (7) Additional medical benefits have surprisingly been found above and beyond the known benefits of mineral supplements. The present compositions have a wide variety of uses in medicine as hereinbefore described and whilst such benefits have been shown applicable to the treatment of human disease, similar uses are proposed in the treatment of animals by way of using the present compositions as veterinary mineral supplements.

The present compositions may be formulated as aqueous solutions and presented for use and/or sale within dropper bottles for convenient addition to foodstuffs, beverages or to water for consumption. Alternatively the compositions can be applied directly to the buccal mucosa for even more rapid mineral metal absorption into the bloodstream.

- 5 Alternatively the compositions may be formulated as capsules containing a unit dose, or presented in tablet form after evaporating or freeze drying the compositions in such a manner that the pH and electrolytic potential can be substantially restored to the preferred values described herein by the presence of acid in the stomach.

CLAIMS

1. A metal-containing composition substantially comprising
 - (i) at least one water soluble metal compound which forms metal ions when dissolved in water,
 - 5 (ii) at least one metal ion modifier as herein defined,
 - (iii) at least one acid, and
 - (iv) watersaid composition having a pH of less than 6 and an electrolytic potential in excess of 10 millivolts.
- 10 2. A composition as claimed in claim 1 wherein said metallic element is one or more of the following mineral metals : copper, magnesium, selenium, iron and zinc.
3. A composition as claimed in claim 1 or 2 which essentially consists of (i) – (iv) as defined in claim 1.
4. A composition as claimed in any preceding claim which consists of (i) –
15 (iv) as defined in claim 1 apart from any unavoidable impurities.
5. A composition as claimed in any preceding claim wherein (i) is an inorganic salt of zinc, magnesium, copper, selenium, iron, nickel, titanium or vanadium.
6. A composition as claimed in claim 5 in which said salt (i) is sulphate, chloride or nitrate.
- 20 7. A composition as claimed in claim 5 or 6 in which said salt (i) is a zinc, magnesium, copper, iron or selenium salt.
8. A composition as claimed in claim 7 in which (i) is zinc sulphate, magnesium sulphate, iron sulphate or copper sulphate.
9. A composition as claimed in any preceding claim in which the metal ion
25 modifier (ii) is at least one metal ion binding, complexing, or sequestering agent.
10. A composition as claimed in any preceding claim wherein (ii) comprises one or more inorganic ammonium compounds capable of dissociating in water into

ammonium ions such as one or more of: ammonium sulphate, ammonium chloride, ammonium phosphate, and ammonium citrate.

11. A composition as claimed in claim 10 wherein (ii) is ammonium sulphate.

12. A composition as claimed in any preceding claim in which (iii) comprises
5 one or more of sulphuric, hydrochloric, phosphoric and citric acids.

13. A composition as claimed in claim 12 wherein (iii) is concentrated sulphuric or hydrochloric acid.

14. A composition as claimed in any preceding claim in which (iv) consists essentially of distilled water or entirely of distilled water apart from any unavoidable
10 impurities.

15. A composition as claimed in any preceding claim in which the pH value is less than 5, preferably less than 4, more preferably less than 3, most preferably less than 2.5.

16. A composition as claimed in claim 15 in which the pH value is 2 or less
15 such as in the range of 1 to 2.

17. A composition as claimed in any preceding claim in which the electrolytic potential is in excess of 20 millivolts, preferably in excess of 50 millivolts and more preferably in excess of 100 millivolts.

18. A composition as claimed in claim 17 in which the electrolytic potential is
20 in excess of 200 millivolts.

19. A composition as claimed in claim 18 in which the electrolytic potential is in excess of 300 millivolts and preferably at least 340 millivolts.

20. A composition as claimed in claim 19 in which the electrolytic potential is in the range of 340 to 400 millivolts.

25 21. A method of making a composition as claimed in any preceding claim comprising dissolving (i) in distilled water, adding (ii) and mixing or allowing to dissolve,

then adding (iii) whilst simultaneously monitoring the pH and electrolytic potential of the composition until a required value of each measurement is obtained.

22. A method as claimed in claim 21 in which (i) is as defined in any one of claims 5 to 8.

5 23. A method as claimed in claim 21 or 22 in which (ii) is as defined in any one of claims 9 to 11.

24. A method as claimed in any one of claims 21 to 23 wherein (iii) is as defined in claim 12 or 13.

25. Use of a composition as claimed in any one of claims 1 to 21 as a
10 medicament for treating or preventing a pathogenic disease or disorder.

26. A composition as claimed in any one of claims 1 to 21 for the preparation of a medicament for treating or preventing a pathogenic disease or disorder.

27. Use of a composition as claimed in any one of claims 1 to 21 as an antimicrobial, antiviral, anti-retrovirus, or antifungal formulation.

15 28. An antimicrobial, antiviral, antiretrovirus or antifungal formulation comprising a composition as claimed in any one of claims 1 to 21 in conjunction with a pharmaceutically acceptable carrier, diluent or excipient therefor.

29. Use of a composition as claimed in any one of claims 1 to 21 for the treatment of water, or predominantly water - containing material.

20 30. Use of a composition as claimed in any one of claims 1 to 21 for the treatment of sewage, industrial or municipal wastes.

31. Use of a composition as claimed in any one of claims 1 to 21 for the treatment of foodstuffs as a disinfectant or bactericide, particularly copper containing such compositions.

25 32. Use of a composition as claimed in any one of claims 1 to 21 for the preservation of plants, flowers, trees or shrubs.

33. Use of a composition as claimed in any one of claims 1 to 21 in the treatment of a metal for coating, sealing, plating or otherwise forming an anti-corrosive layer upon a metallic substrate.

34. Use as claimed in claim 33 wherein the composition contains one or more
5 of copper, nickel, titanium or vanadium.

ABSTRACT"METAL-CONTAINING COMPOSITIONS, PREPARATIONS AND USES"

A metal-containing composition substantially comprising

- 5 (i) at least one water soluble metal compound which forms metal ions when dissolved in water,
- (ii) at least one metal ion modifier as herein defined,
- (iii) at least one acid, and
- (iv) water
- 10 said composition having a pH of less than 6 and an electrolytic potential in excess of 10 millivolts.

Such compositions have uses in the prevention and/or treatment of pathogenic disease or disorder, as foodstuff supplements, in the treatment by disinfection of meat and other foodstuffs, in the coating, sealing and plating of metals, and treatment of water

15 and sewage.